Contents

Comment Group 1

- A. Comments Related to Fact Sheets
- B. Comments Pertaining to Site-Specific Action Levels and Bioavailability
- C. Comments Pertaining to Current Air Quality
- D. Comments Pertaining to the RMAP Implementation and Ongoing Biomonitoring Program

Comment Group 2

- A. Comments Pertaining to the Goals and Purpose of the Health Studies
- B. Comments Pertaining to Public Involvement
- C. Comments Pertaining to Environmental Justice
- D. Comments Pertaining to Independence of Study/Investigators and Need for External Peer Review
- E. Comments Pertaining to Specific Study Design Elements of the Draft Work Plan
- F. Comments Pertaining to the Study Focus on Exposure vs. Health Outcomes
- G. Comments Pertaining to Focus on Lead
- H. Comments Pertaining to the Precautionary Principle
- I. Comments Pertaining to Other Various Issues

Comment Group 1 -

Below are general groupings of comments received to date that relate primarily to topics that will be addressed outside of the Superfund Health Study and draft Work Plan revisions. For each grouping of comments, excerpted comments from original comment submittals are enumerated. The shading or font color for each group heading corresponds to shading or font colors in the attached chronological summary of all comments submitted.

A. Comments Related to Fact Sheets

- Comments are specific to information provided in Fact Sheets referenced in the initial health study work plan.
- Responses will be referred to the primary group/organization responsible for development of specific Fact Sheet.

(Note to Readers: The main points under comments 1 and 2 below are essentially the same, but were submitted by the same individual to EPA and BSB on two different dates – December 14, 2012 and December 29, 2012.)

1. As a resident of the Greeley Neighborhood Community I am most concerned about what Fact Sheet No. 5 does not say.

It does not say:

- What is the measurement of fine airborne particulate matter (PM2.5) by month? (Our greatest repertory problems are during the months of July, August and September, the high dust months not the high smoke months.
- What are the contaminants of concern that are not even being monitored? (Our greatest concerns are air-born heavy metals and crystalline silica.)
- What period "Figure 2, Chemical Makeup of PM2.5 in Butte" covers? (Was this from the 2007-2008 period when the study was made, when Average Measurements, were below the 24-Hr Standard +35 micrograms/cubic meter, or from a later period?)
- Why Figure 2, does not show any metals analysis? (When a sample of dust collected from the roof of a residence near the monitoring site contained significant concentrations of metals.)
- Why the only disease of concern seems to be cancer? (Our school nurses indicate that other air quality related diseases seem to be on the rise. We were recently told that Butte has more Ghost Signs than most any other city in the country. But I have noticed that we also seem to have more people sucking oxygen out of little portable containers than in any other of the ten communities of the world I have lived in, in my life time

So if the Team is going to give us a fact sheet, please include all of the facts, and cover all of the major concerns.

2. As a resident of the Greeley Neighborhood Community I am most concerned about what Fact Sheet No. 5, Fact Sheet No. 6 do not say, and what the Remedial Design Work Plan does not cover. It does not say/cover:

- What is the measurement of fine airborne particulate matter (PM2.5) by month? (Our greatest repertory problems are during the months of July, August, September and October, the high PM10 dust months not the high smoke months.
- What are the contaminants of concern that are not even being monitored? (Our greatest concerns are air-born heavy metals and crystalline silica.)
- What period "Figure 2, Chemical Makeup of PM2.5 in Butte" covers? (Was this from the 2007-2008 period when the study was made, when Average Measurements, were below the 24-Hr Standard +35 micrograms/cubic meter, or from a later period?)
- Why Figure 2, does not show any metals analysis? (When a sample of dust collected from the roof of a residence near the monitoring site contained significant concentrations of metals.)
- Why the only disease of concern seems to be cancer? (Our school nurses indicate that other air quality related diseases seem to be on the rise. We were recently told that Butte has more Ghost Signs than most any other city in the country. But I have noticed that we also seem to have more people sucking oxygen out of little portable containers than in any other of the ten communities of the world I have lived in, in my life time

So if the Team is going to give us a fact sheet, please include all of the facts, and cover all of the major concerns.

- 3. I would offer a comment on the Health Study Remedial Design Work Plan Work Plan presented by the Butte Silver Bow Health Department and prepared by Environ International with respect to the assessment that "lung and bronchus cancers were not elevated in BSB during the three time periods from 1981 through 2010". If you examine Figure 6, you can clearly see that the incidence of lung cancer is elevated for BSB above the state and national incidence for the period 2001 2010. During that same period, Figure 10 shows the mortality due to lung cancer is significantly elevated over the state average. We must remember that the state average also includes figures from Libby, Montana, where the incidence of lung cancer is extreme due to asbestos exposure.
 - It is incumbent that the question be asked as to the cause of this increased incidence of respiratory disease in the county during the period from 2001 2010. The cause may or may not be related to BPSOU factors, but to understate or ignore the increased incidence of lung disease in BSB is a disservice to the citizens of BSB who are living with whatever conditions are causing them to suffer this problem.
- B. Comments Pertaining to Site-Specific Action Levels and Bioavailability
 - Comments relate to the validity of the site-specific action levels and bioavailability data.
 - Will EPA take the lead on these responses?
- 1. Are the Superfund action levels in Butte protective of human health and the environment? What data warrants the conclusion that the action levels set by EPA are in fact, protective of human health?
- 2. Need to thoroughly assess, in an effective, reliable and valid manner, issues related to the bioavailability of heavy metals in Butte.
- 3. I still don't see why EPA has not adopted the new 5 microgram standard vis a vis the action levels in Butte. EPA's failure to do so continues the disparate toxic burden that low-income citizens must

endure in Butte. In Butte, low-income citizens endure a disparate exposure level to lead compared to the non-poor and low-income citizens are less able to withstand the health effects of lead expsure than the non-poor. Why is EPA dragging its feet? EPA, when it suits them, has always waxed eloquent in supporting the findings of the CDC? Why not now? Why haven't the action levels changed to conform to the CDC reccommendations? Why is this public health issue and this environmental justice issue being ignored? Is it because the EPA doesn't want to go to the trouble of reopening or modifying Records of Decision at sits such as Butte?

- 4. The question: Is the reduction of bioavailability rates for arsenic valid? needs to be answered by the Health Study.
- 5. The protectiveness of the site specific action levels in Butte needs to be part of the Health Study. If the action levels are not protective, continuing to use them is unjustifiable.
- 6. The bioavailability of the toxics on the Butte Hill needs full and complete study.
- 7. The action levels were established from one study that used only a handful of pigs as subjects to determine bioavailability. The pigs were gavage fed contaminated soil in a method that does not mimic any kind of natural process. The direct leap from force feeding pigs dirt to my kid's uptake seems like a stretch. There is also another study conducted at the same time that shows a much higher bioavailability that was apparently ignored by the EPA (R. Poppeng et al.1990).
- 8. Based in part on the often sited bioavailability study, an action level of 1200 ppm was established for Pb concentrations in soil. This is dramatically higher than the EPA's standard of 400 ppm for play areas.
- 9. As stated in the draft, The CDC and EPA are moving toward a BLL action level of 5 (ug/dL) for Lead. The soil concentration action levels are based on the old value of 10 (ug/dL). When will these levels be revised?
- C. Comments Pertaining to Current Air Quality
 - Comments relate to air quality concerns that need to be addressed.
 - Responses will be developed by BSB in relation to the Non-Superfund Health Study.
- Nuisance Dust and General Air Quality is a problem in dry, windy, and disturbed areas, like Butte, but we are not assessing all these problems since the changes from Dust Jars/Teflon Plates to Total Suspended Particulates (TSP) and to PM10 and PM2.5 combustion product assessment methods. We should reconsider some of the older air quality methods that measure larger particulates (nuisance dust?), and analyze for contaminants such as lead and arsenic.
- 2. As a resident of the 1900 block of Locust Street in Butte, Montana, I would like to express my appreciation for extending the scope of the BPSOU Health Study to include a preliminary evaluation of the health effects of the ongoing mining operation. You have been very responsive in listening to the concerns of residents whose homes have been receiving fine particulate dust from the crushing operation at the mine and chemical odors from the concentrator. While a thorough evaluation of the impacts may be beyond the possible scope of the current study, your efforts will identify whether particular aspects of these problems represent health concerns.

 Some residents on my block have lived there since before the Anaconda Company was sold to ARCO. While they suffered some impacts from dust, they report that current levels they are

experiencing are unprecedented. Further, there was formerly no odor associated with the operation until the current owners first occupied the site. I have lived there for over ten years and, until recently, almost never experienced the sulfide odor. Now, it is a regular feature of the outdoor air.

It is my understanding that the study you are undertaking will focus on PM2.5 sized particles, since current regulations are based on that fraction. While I agree that investigating respiratory exposures in that size range is important, limiting data collection to that size range ignores the possibility that children could be exposed to heavy metals through ingestion of dust particles by other routes, similar to lead exposures. I would suggest that the PM10 monitor at the Greeley School site be used to collect data in that size range and that a chemical and mineralogical analysis be conducted on a composite sample of that material. Basically, the PM10 study should answer the questions, "What is it?" and "How much of it is entering the neighborhood?" In addition to the elements being analyzed for the BPSOU purposes, the following elements should be quantitated:

Co - cobalt CAS NO. 74440-48-4

Ni - nickel CAS NO. 7440-02-0

Mo - molybdenum CAS NO. 7439-98-7

U - uranium CAS NO. 7440-61-1

Th - thorium CAS NO. 7440-29-1

Further, the alpha, beta and gamma radiation activity of the sample should be determined.

Again, thank you for extending the range of the current study to include the Greeley neighborhood.

- D. Comments Pertaining to the RMAP Implementation and Ongoing Biomonitoring Program
 - Comments relate to how the RMAP program is being implemented, including biomonitoring elements.
 - Will BSB take the lead on these responses?
- 1. It is difficult to know where to start or end my comments regarding the health study. Many of my concerns lie in the original action plan, and are not a direct comment on the study. I am relatively new to Butte, but I have done my best to educate myself on the issues. I am very interested in the outcome for many reasons, not least of which is I am a father of two boys living in uptown. Our home was one of the properties remediated by RMAP. The folks who did the sampling and the abatement were very helpful, efficient and informative and I have no complaints with how they did their jobs. I do, however, have concerns with the process. The following is a sample of my concerns, but for a more complete discussion, I would be happy to participate in an interview.

 Our home was tested for Lead, Arsenic, and Mercury. Action levels were exceeded for Pb in one portion of our yard and action levels were exceeded for Pb and As in our attic dust. I have a number of concerns with this process:
 - The yard samples were averaged over a number of samples. This opens the possibility of seriously contaminated soils averaged with non-contaminated. For instance: in the portion of my yard that was not flagged, a Pb level of 498 ppm was found. This could easily be skewed by several samples from areas of soil imported for gardening.

- Only areas of our attic with access were remediated. This left many areas with dangerously high Pb and As levels. In a drafty house as old as ours (built in 1890) dust certainly migrates within the house.
- I had to make the call to start the process with RMAP. I was only aware of it because of my own research. How will the study attempt to quantify all of the residents who, for one reason or another, have not had their homes or their blood tested? Beyond simple ignorance of the issue, there is a social stigma associated with heavy metal exposure.

Soon after the remediation I attempted to establish a baseline for our blood lead and urinary Arsenic levels. I called the health department and was referred to WIC. At first, WIC claimed only my 9 year old would be eligible for testing. After some arguing they agreed to test my older son and myself. WIC did not offer Arsenic testing. I called the Health Department again to request As testing. At first they claimed they knew nothing about it. After two more calls with two different people I was told they did not offer it and I should request it from my personal Physician. This testing process, which seems to be the basis of the health study, is seriously flawed.

- The lower detection limit of the BLL test at WIC is 4 (ug/dL). My sons and I all fell below this limit so we were unable to establish a baseline.
- It is true that high BLLs are of greatest concern for young children, but Lead can affect anyone. The stated principal study question asks if the program has been effective in mitigating harmful exposure in the Butte community. I feel this should include everyone in the community, with particular attention paid to the most vulnerable.
- The CDC is moving toward an action level of 5 (ug/dL) and has recognized negative effects with levels as low as 2(ug/dL). Shouldn't the Health Department be testing for lower levels than 4?
- I did not find the process to be easy or inviting. If I had not taken the initiative, I would not have known about it. As a single father I have no reason to visit WIC, and they seemed to think it was strange that I would. The person who tested me said she had never tested an adult.
- Without the data from kids with levels from 0-4 ug/dL, the study is seriously flawed.
- The claim that As testing is offered to residents with high levels in their residence is false. Even after repeated requests I was not offered urinary testing.

This leads to my primary concern with the study. It does not take into account people like me. I naively believed that the RMAP would actually clean up my property. When it became obvious they had not, I resorted to other methods. I discourage my children from playing in the soil, I do not garden, I don't allow my children in portions of our home and so on. I do not believe this is fair. The responsible parties should have cleaned up the contamination to level that is safe for normal activity. Now because my children are not inflicted with high BLLs the study will call RMAP a success? What a joke. The only way to determine the effectiveness of the program is to actually and thoroughly remove the contaminants. I would like to see my own and my neighbor's properties remediated to a level where we would feel comfortable gardening and allowing children to play outdoors. Then a secondary measure of success could be to monitor the health of the community as a whole. The health study should be conducted by a third party, and should have a wider focus than just those who volunteer for BLL testing. I hope these comments are taken seriously and I hope I can be of further assistance if need be.

Comment Group 2 -

Below are general groupings of comments received to date that relate primarily to topics that will be addressed in the Superfund Health Study and draft Work Plan revisions. For each grouping of comments, excerpted comments from original comment submittals are enumerated. The shading or font color for each group heading corresponds to shading or font colors in the attached chronological summary of all comments submitted.

A. Comments Pertaining to the Goals and Purpose of the Health Studies

- Comments relate to the need for clarity regarding why the studies are being done and how they will result in changes to the Superfund cleanup.
- Response will provide clarity and context for the current study and its relationship to future studies. Revisions to the work plan will also be made to clarify these points.
- 1. The goal of future health studies needs clear articulation. So far, other than complying with the terms of the EPA's unilateral order, the goal and purpose of these future health studies is unclear. Why are these health studies being performed, other than to satisfy the terms of the EPA's unilateral order? How will these health studies impact Superfund cleanup in Butte? If diseases related to heavy metals exposure have not decreased but in some cases increased since the inception of Superfund in Butte, will the ROD(s) for Butte, particularly Butte Priority Soils be reopened to be more protective?
- 2. In all of the discussion about the direction of future health studies, it is important to remember that:
 - a. Butte does have a heavy metals exposure problem due to past mining activity.
 - b. The heavy metals present in Butte do pose a threat to human health and the environment.
 - c. Study after study has established that the toxics of concern in Butte are harmful to human health, i.e. they adversely affect human health. If they did not, why have Superfund in the first place?
 - d. Superfund was created to lessen, mitigate, remediate or remove these threats.
- 3. Overall, CTEC supports the near-term focus on evaluating biomonitoring data, and we are encouraged to see that the blood lead and other relevant data are being incorporated into a useable database. This is relatively easy to do and is perhaps most directly applicable to established EPA procedures for assessing exposure and risk. However, we find that the draft health plan does not fully live up to the mandated expectations.
- 4. No longer-term studies or conceptual strategy proposed: Section 4.1 of the Final Multi-Pathway Residential Metals Abatement Program Plan (RMAP) states, "Butte-Silver Bow will perform public health studies every five years for a period of 30 years", p. 7. No studies beyond a report next year evaluating existing biomonitoring data are proposed. Only vague reference is given on page 1 of the Draft Plan to focusing "initial study resources" on evaluation of currently available information.
- 5. Narrowly defined and poorly articulated study question: The study question is not clearly presented until page 16 of the Draft Plan (though shades of it are mentioned on pages 3 and 13). This presentation of the proposed study objective comes too late in the document and is too poorly constructed relative to typical scientific norms to effectively guide the document. Structurally, it

seems inappropriate to have the study question dependent upon available data. Technically, the focus on exposure rather than health and the focus on lead, arsenic and mercury, seem too narrow. The types of questions that Terri Hocking related in his guest opinion to the Montana Standard are more meaningful to CTEC and more consistent with the proper structure of research questions (though we do not intend these to be CTEC's proposed list of study questions):

- "Do we have higher cancer rates than other communities, and are they caused by environmental contaminants?
- Why are the contaminants of concern as defined by EPA limited to lead, arsenic, and mercury?
- Are there cumulative effects of environmental contamination of one or more chemicals of concern?
- Is our drinking water safe?"

The drinking water concern is particularly relevant to those residents using well water. Some of these types of questions are addressed, in part, in the Draft Plan, but is difficult to discern because of the structure of the document. Some of the needed information is provided in Section 2.1 while other information related to the same point is provided in Section 2.3. Regardless, we do not ask that the document must be re-written (other than as needed to address our specific comments below). We reiterate our shared understanding of the central importance of evaluating the biomonitoring data. However, the narrowly defined study question in combination with the structure of the document seems to distract from a compelling and coherent assessment of the above listed questions which are more central to the concerns of CTEC and the broader Butte community. Overall, the work reflects the efforts of applied environmental scientists and policy makers rather than public health research scientists.

- 6. p. 14-15, Section 2.2, Study Objectives and Approach: Three different metrics are proposed to assess the "efficacy of the RMAP": summary statistics by year, time matched comparisons with other population(s), and comparisons across neighborhoods. However, the reasons for these metrics are not stated. Moreover, it's unclear how the "efficacy of the RMAP" is to be assessed. Some restatement of the quantitative metrics for "mitigating harmful exposure" need to identified, such as those listed on page 7 of the RMAP with due consideration to recent reconsideration of what constitutes safe blood lead levels. It can then be shown how the three proposed metrics relate to this broader goal. While the first metric makes some sense for reasons that extend beyond the explanation provided in the text, the need for the next two metrics are not clear. The bottom line is that blood lead levels need to remain below acceptable levels, on a community wide basis, consistent with the expressed professional judgments of the CDC and EPA. We appreciate that lead exposures can remain elevated for the reasons stated at the close of this section on page 15; however, the section should end with criteria that would define unacceptable levels and the kinds of actions that would be considered to remedy such a finding. [Note: we recognize that some of this requested information may be covered in other sections, such as Section 2.3.2, page 17, but the repetitive structure of the document makes it hard to put it all together in a way that is clear, concise and not open to contradiction.]
- 7. p. 16, 2nd paragraph (not including bullets), Section 2.3.1, State the Problem: Verb tenses throughout this paragraph seem amiss with past and future work in confusing ways. Moreover, the

- text's flow seems to be from past to future to present actions. Key here is the need to clarify what the agencies really propose to do regarding support and input to the study development. Is this referring only to this work plan and the proposed 2013 report, or is it to the future 5-year health studies. We suggest it should include the latter, and in either case, what kind of support is needed?
- 8. p. 17, 1st paragraph, Section 2.3.2, Step 2: Identify the Goal of the Study: Public participation should be integrated into this description for how any RMAP deficiencies are identified and responded to. In particular, CTEC seeks an active role in encouraging participation in the voluntary cleanup program. Also, the roles and responsibilities of various agencies in supporting/approving of response actions should be stated.
- 9. As currently articulated, it is not clear what will be the focus of the Health Study. The focus of the Health Study has been all over the place since it was announced a number of months ago. Is it focusing on just evaluating the RMAP program? Is it focusing on investigating the health effects and remediation efforts concerning all toxics of concern in Butte—lead, mercury and arsenic? Will it evaluate the health protectiveness of institutional controls and the waste left in place solution including caps? Will it investigate the health effects of the contaminants at the Poll Plant? Will it investigate the protectiveness of the remediation efforts at the Poll Plant? Will it investigate the general public health of Butte, including life style, diet, smoking, alcohol consumption, etc.? Depending on which official is speaking, the focus of the study wanders. There needs to be a clear, unambiguous statement of the focus of the Health Study.
- 10. It is unclear what is the purpose of the study. Why are we doing the study, other than it is mandated under the UAO? Is it to evaluate the effectiveness of the Butte Superfund cleanup? Is it to reach general conclusions regarding the public health of Butte? How does it relate to the recently completed Five-Year Review? There needs to be a clear, unambiguous statement of the purpose of the study.
- 11. There needs to be a clear statement regarding how this study will be used and how it will affect public health policy. What is to prevent it from becoming just another study that sits on a shelf?
- 12. I do not see the recent health study as being much different. The residents of Butte deserve and want the facts and the truth. The purpose of the health Study should be to determine the facts as they exist and then to take the necessary steps to address the facts. It appears the purpose of this study is designed to justify the irresponsible Superfund cleanup in Butte and not to address the health issues facing Butte that the residents of Butte deal with on a daily basis. I hope I am wrong.
- 13. Openness, Objectivity and Validity: Drawing in part from potential inadvertent biases related to EJ, we have expressed a number of concerns pertaining to scientific objectivity and validity. These concerns draw from an overall lack of open inclusion in the study design that is needed to ensure that multiple perspectives on the problem are addressed. Prior comments along these lines include:
 - Clarifying commitments on study scope beyond the current blood lead study.
 - Improved contextualization and expression of the study question(s) for the current proposed blood-lead study.

B. Comments Pertaining to Public Involvement

- Comments relate to the need for more meaningful public input and participation in designing the study and perceptions of "secrecy" surrounding the study design.

- Response will include detailing the ways in which public input to the process has been sought and clarification of the study design development process that has occurred with participation by the planning team members. Revisions to the work plan will be made to clarify the public involvement efforts included in the study design process.
- 1. We were promised full, meaningful and efficacious public involvement. This whole process has been characterized by secrecy on the part of EPA, MDEQ and the Health Department. The so called "listening sessions" are designed, not to solicit meaningful public input, but to "sell" the public on the Health Study. Using the technique of "listening sessions" is a well tried and used technique to stifle public comment and place the public in the role of passive received of "information" from the EPA and PRPs. Such as approach is bad public policy decision making and is contrary to the EPA's own mandates regarding public involvement.
- 2. CTEC appreciates the opportunity to comment on the Draft Public Health Study Remedial Design Work Plan for the Butte Priority Soils Operable Unit (Draft Plan). We believe that a scientifically rigorous health study can do much to develop an objective and commonly recognized understanding as to whether the Superfund Program is providing for a safe and healthful environment. Given Draft Plan's overall importance to the Superfund project, we are, as you know, quite disappointed that you decided to take a more limited approach to public participation thus far. Moving forward, we wish to establish a more deliberative and collaborative working relationship. Accordingly, we submit these comments recognizing there are some things we may not yet understand and in a sincere effort to be constructive.
- 3. Minimal opportunities for future public involvement: Section 2.4.2 of the Draft Plan provides minimal opportunities for public involvement. While this minimal approach is perhaps adequate for the evaluation of biomonitoring data, with modest expansion as indicated in our Specific Comments, it is not sufficient to address the longer-term study needs as reflected by the kinds of questions mentioned in comment 3 above [Note: "comment 3 above" references the November 30, 2012 CTEC comment letter]
- 4. General Comment Summary and Proposed Actions: The core issue underlying our General Comments is the desire to constructively identify what kinds of epidemiological studies might be done in the future that would improve our understanding of the health protectiveness of the remedy. CTEC is concerned that thus far there has been inadequate involvement by qualified epidemiological researchers. A highly polarized, dueling science kind of debate has been going on this past year, often through the media, that has undermined public understanding of and trust in the science. While we support moving forward with the biomonitoring assessment, CTEC proposes a separate track to assess possible options for future 5-year health studies. We believe this process needs to start by more thoughtfully considering the kinds of questions the studies need to ask, better understanding the limitations of what existing epidemiology can do to answer the study questions, what kinds of new epidemiology data is maybe needed, and what other kinds of studies such as ongoing biomonitoring should be conducted into the future. Moreover, we strongly believe that a well designed, deliberative process of engagement between the agencies and affected, interested community members will do much to achieve a well-informed, common understanding of

- the healthful nature of the Butte community and any additional remediation needs for the Superfund Program moving forward.
- 5. p. 21, last paragraph, Section 2.4.2 Task 2 Community Outreach: Given CTEC's strong interest in this Draft Plan, the nature of our questions, and the redundant structure of the Draft Plan that makes it hard to follow (see the next comment for example), we request that the proposed open house also include a presentation and group discussion on the proposed approach. We think that will be the best way to resolve many of our comments.
- 6. p. 23, paragraph 5, Section 2.4.5 Task 5 Quality Assurance Review: CTEC requests that public review be added to any and all parts of this Draft Plan that involve decision-making and agency approval.
- 7. My First comment is a question: How is the Public suppose to comment when they have not been informed when, where, why, and way they are to comment? I would have expected that the same procedure as was used by the BNRC to inform The Public and invite The Public to their meetings would have been used by this committee.
- 8. The process of developing and conducting the Health Study needs to be open and transparent. There needs to be full compliance with Montana Open Meetings law as well as federal law on the subject. Meetings pertaining to the design and conduct of the Health Study need to be open to the public with due notice of these meetings posted in the media. The public needs to be afforded the opportunity to comment and participate in these meetings. So far the process of developing the Health Study has been marked with excessive secrecy.
- 9. The process has been marked by secrecy. The public has had to constantly demand information about what was going on. Grudgingly, the EPA has released tidbits of information. How can the public participate in Superfund decision-making if it does not know what is happening? It took me countless emails just to find out, for example, who was on the Health Study advisory board and when it was meeting and what were the results of those meetings.
- 10. Butte citizens question the independence and validity of the study. It is the old story of the EPA evaluating itself and finding that it has done a good job. This Health Study has no credibility in the community. The EPA publicly laments a lack of citizen participation. Why should citizens participate when their comments have no efficacy? Why should citizens participate when they are criticized for participating? Time and again I have been told by members of the public that participation in Superfund is a total waste of time and effort. Perhaps it is time for Region 8 to become more involved. The above was not always the case. Years back the EPA in Montana was much more open to public input. Today, it is a defensive, hunker down agency. At a minimum, the Montana Office should have a public meeting and respond publicly to the comments it has received in addition to putting out a responsiveness summary. The whole Health Study design and execution should be subject to independent peer review.

Will things change? We will see. We will see how seriously EPA takes the comments it receives. We will see if the EPA responds in a substantive manner to the comments it receives. We will see if the EPA makes changes in the Health Study Work Plan to respond to citizen input. We will see if EPA takes seriously its commitment to meaningful public involvement and environmental justice.

I am not optimistic. It is hard to hold an agency publicly accountable. We can't vote agency personnel out of office. I suspect all we will get is some perfunctory response to citizen input. Hopefully, I will be proved wrong.

- 11. All test results need to be made publicly available.
- C. Comments Pertaining to Environmental Justice
 - Comments relate to failure of the study design and development process to address environmental justice concerns, meaningful involvement of the public, and low-income citizens within Butte, specifically.
 - Response will include detailing the ways in which environmental justice considerations have been included in the development process and the study design. A section detailing these considerations will also be added to the revised work plan.
- 1. On October 31, 2012, the Butte Silver Bow Health Department released a draft "work plan" for their study of the health effects of contaminants of concern at Butte area Superfund sites. This work plan was mandated pursuant to an EPA unilateral order regarding Butte, Montana area Superfund sites.

While I will have substantive comments regarding the Butte/Silver Bow Health Study "work-plan" in due course, I wish to complain with utmost vigor about the neglect of the "work plan" to address or consider, in any substantive manner, issues related to environmental justice in the design of the Health Study "work plan".

Even though Butte has a disparate number of low-income citizens located within the Superfund site, Environmental justice is mentioned only twice in the "work plan" and neither time in a substantive way, i.e. nothing regarding the design and execution of the "work plan" specifically addresses environmental justice issues. The poor are never mentioned in the "work plan" nor are low-income citizens. The poor and low-income citizens are ignored, contrary to the EPA's environmental justice mandate and promises made by that Montana Office of EPA that environmental justice issues would be a major focus of the health studies.

- 2. Citizens were promised that environmental justice concerns would be at the forefront of the design, methodology and conduct of the health study. Environmental justice is ignored.
- 3. How does exposure to the toxics of concern affect low-income citizens that tend to be concentrated in the Butte Priority Soils Superfund site?
- 4. Need to consider the effect of heavy metals exposure on low-income citizens.
- 5. So far EPA has failed to assess the risks to low-income citizens posed by the toxics of concern in Butte. The differential effects on low-income citizens of exposure to the toxics of concern have been ignored. "In epidemiological studies, the term confounding is used to describe the situation where an association between the factor of interest and the disease outcome is explained by the association of both these factors with another variable, the confounder, which itself is either a cause or closely related to the cause of the disease. Age and social class, for example, are commonly regarded as confounders as they are strongly related to disease occurrence and are also related to a wide range of environmental exposures." [Lesley Rushton and Paul Elliott, Institute for Environment and Health, "Evaluating evidence on environmental health risks," British Medical Bulletin [2003]68 (1)]

Any health study that fails to consider the health effects of toxic metals exposure on low-income citizens will be seriously incomplete as well as violating the requirements of environmental justice. Butte's low income citizens are at special risk in terms of the effects of exposure to heavy metals and that risk must be fully assessed and mitigated. "Assessment of the impact of a potential adverse health effect from an environmental pollutant is dependent on an understanding of several issues, including: the variability and susceptibility of the potentially exposed population, for example, regarding sub-groups of the population that might be at especial risk due either to the pattern and distribution of exposures in the population, or to non-environmental factors that might influence the risk of disease." (Ibid.) Different areas in Butte have different levels of toxics exposure. Butte's areas of greatest toxic concentration correspond to areas that are home, disproportionately to the rest of Butte and Montana as a whole, to low-income citizens. Therefore, environmental justice concerns must be at the forefront of any future health studies in Butte.

- 6. So far environmental justice issues and concerns seem to be missing from the work plan for conducting the Health Study. The current work plan is silent on environmental justice. It is not clear how or whether environmental justice concerns/issues are going to be specifically addressed by the proposed Health Study. I would ask that the final version of the Health Study work plan specifically address environmental justice issues. I would ask that the final version of the Health Study work plan specifically state how the Health Study will address environmental justice concerns. I would ask that there be a specific, discrete and identified section of the Health Study devoted to addressing environmental justice issues.
- 7. The EPA has a mandate to consider and to promote environmental justice in all of its activities which would, of course, include Superfund. A central focus of the Butte Health Study mandated by the Montana Office (Region 8) of EPA's unilateral order is central Butte—an area encompassed under the designation of Butte Priority Soils OU. Central Butte has a disproportionate number of low-income citizens. Low-income citizens within the Butte Priority Soils site endure a disparate toxics burden which is not considered or addressed by the Health Study work plan.

Environmental Justice and Uptown/Central Butte

The EPA has a mandate to promote environmental justice in all of its activities.

The EPA defines environmental justice as "the fair treatment and meaningful involvement of all people regardless of race, color, national origin or income with respect to environmental laws, regulations and policies." No minority or low-income population should bear a disproportionate toxics exposure burden. EPA Administrator Lisa Jackson has made promoting environmental justice a top EPA priority. Low-income citizens are a particular target for environmental justice activities. Given that low income citizens are concentrated in Uptown/Central Butte, the toxic substances in Uptown/Central Butte disproportionately impact Butte's low-income citizens, who are concentrated within uptown/central Butte

Extent of Poverty in in Uptown/Central Butte

In Butte-Silver Bow, the poverty rate is at 15.8%, which is higher than both the national and state rates, and has risen almost a full percentage point since 2000. (U.S. Census Bureau) According to the U.S. Census Bureau, over 25% of Butte families with children under the age of

five years have incomes below the official poverty line. 21% of Butte children live below the poverty line. (Butte Silver Bow Health Department, Community Needs Assessment.) According to the Montana Department of Public Health and Human Services, about 2.4% of Butte citizens are receiving Temporary Assistance for Needy Families compared to the state average of 1.89%. Over 10% of the Butte population was receiving food-stamps compared to 7.56% statewide. Thirty-seven percent (37%) of the county population is at or below 200% of the federal poverty line, qualifying them for low-income assistance programs like Low Income Energy Assistance (LIEAP) and a sliding fee at the Community Health Center. (2011 Community Health Improvement Plan—Butte Silver Bow Health Department)

Most of Butte's poor live in uptown Butte, the area encompassed by the Superfund site—Butte Priority Soils. Within Butte/Silver Bow, there are pockets of deep poverty which tend to occur in uptown Butte. Forty percent of Butte-Silver Bow's Census Block Groups (17 out of 43) had poverty rates higher than the overall county rate in 2000 that ranged from 15% to 61%. Of the 17 high poverty Block Groups, ten (or 59%) were located in Census Tracts 1 and 2, inside the older town site, which is the area encompassed by the Butte Priority Soils Superfund Site. These two tracts contain 52% (2,550 people) of the county's poor while containing only 29% of the total population (Butte-Silver Bow Growth Policy).

The poor in Butte's central district do have to endure a disproportionate toxics exposure and risk burden. Much of the housing stock in uptown/central Butte is in a state of decay and often has contaminated attic and indoor dust, contaminated yards and lead based paint in the home. Consider the fact that of the 1200 houses in Butte that have a high risk of lead exposure, the vast majority are in the Butte Priority Soils site.

Given EPA's mandate to consider and promote environmental justice, it is a glaring weakness in the Health Study work plan that there is no mention of environmental justice nor is there any special consideration given in the work plan to the issue of environmental justice in the Butte Priority Soils OU.

As designed, the current work plan will actually have a discriminatory effect against low income citizens. For example, the use of rolling averages whereby low-income and non-low-income citizens are conflated together for purposes of the study has a discriminatory effect against low-income citizens. The failure of the Health Study to consider mortality rates or incidences of disease related to the toxics found at the Butte Priority Soils site has a discriminatory effect against low-income citizens residing within the Butte Priority Soils site. The failure of the study to consider the bio-accumulative, synergistic and cumulative effects on human health of the toxics found at the Butte Priority Soils site has a discriminatory effect against low-income citizens residing within the Butte Priority Soils site.

This lack of attention needs to be corrected. There needs to be specific consideration of the health effects of the toxics found within the Butte Priority Soil OU on low-income citizens residing with the Butte Priority Soils site.

- 8. As described in the work plan, the Butte Health Study mandated under an EPA unilateral order is not a health study. At best, it is another exposure study.
 - Yet, it does not look at toxics exposure specifically as such exposure pertains to low-income residents of the Butte Priority Soils OU. Therefore, the Health Study work plan is at variance with

EPA's mandate to consider and promote environmental justice. The work plan needs to be changed to remedy this defect.

Environmental Justice Failures:

- 1. The work plan does not examine the health effects of multiple individual exposures to multiple toxics within the Butte Priority Soils OU, which is the focus of much of the Superfund part of the Health Study. The Health Study seems to concentrate exclusively on lead exposure. Low-income residents residing with the Butte Priority Soils OU are exposed to numerous Superfund related toxics—lead, arsenic, mercury, cadmium, zinc, copper, etc. The study ignores the other toxic threats by concentering exclusively on lead. Given that the immune systems of low-income citizens tend to be more compromised and more susceptible to the adverse health effects of exposure to the toxics listed above, the failure to consider the health effects of exposure to multiple toxic threats regarding low-income citizens is a serious environmental justice lapse. It could well be that an exposure level that is deemed "safe" for a non-low-income person would be harmful to a low-income citizen. By filing to consider the disparate impact on low-income citizens of the toxics found within the Butte Priority Soils OU, the Health Study, as currently designed, continues to perpetuate a disparate toxics burden on low-income citizens and is, therefore, contrary to EPA's environmental justice mandate.
- 2. Another serious environmental justice failure is that the proposed Health Study fails to look at the synergistic, bio-accumulative and cumulative effects of multiple exposures to all of the toxics of concern on low-income residents of the Butte Priority Soils OU. Low-income residents are not exposed to lead, arsenic, mercury, cadmium etc. as isolated toxics. Low-income citizens are exposed to these toxics at the same time. To look just at lead, for example, is a misrepresentation of the toxics' picture that low-income citizens face.
- 3. Low-income residents have been excluded from the planning of the Health Study. The Health Study advisory board has no representative from any low-income group. No attempt has been made to specifically address the health issues related to Superfund that are of particular concern to low-income citizens. No specific outreach to low-income citizens is planned or has been conducted.
- 4. By mixing exposure data from low-income areas with exposure data from non-low-income areas, the study will misrepresent the specific toxic effects on low-income citizens. The Health Study needs a specific focus on the health effects of the toxics found at the Butte Priority Soils OU on low-income residents, specifically.
- 5. The Health Study work plan needs to document what specific outreach programs will be pursued relative to low-income citizens. What specific endeavors will there be to include and meaningfully involve low-income citizens in the planning and execution of the Health Study? So far, no such outreach activity is discussed. Low-income citizens are on the outside looking in, which is contrary to EPA policy.

The Butte Priority Souls OU, because of its disproportionate number of low-income citizens, should be a focus of environmental justice activities by EPA. It is time for EPA to get serious about addressing environmental justice concerns and the current Health Study would be a good place to start.

- 9. The EPA also needs to adopt action levels for the toxics of concern in Butte that specifically apply to low-income citizens who are more susceptible to the effects of lead poisoning than the non-poor. The failure to do so perpetuates environmental injustice.
- 10. The composition of the Health Study Advisory Board needs to be changes and a representative of Butte's low-income community appointed to this board. Environmental justice demands that this takes place. At present, low-income citizens are meaningfully excluded from the process of developing and executing the Butte Health Study.
- 11. I don't need to repeat the details of EPA's written commitment, in terms of policy and procedure, to "meaningful public involvement" and to promoting environmental justice.
 - We will see if the EPA's reaction to the comments received is congruent with the agency's written commitment to promote efficacious public involvement and to promote environmental justice. If the public comments simply get "blown-off" and become only the subject of a perfunctory responsiveness summary, Butte citizens will see once again that the EPA only pays "lip-service" to meaningful public involvement in Superfund decision-making and to environmental justice.
- 12. Although central Butte has a disproportionate number of low income citizens, environmental justice concerns have been ignored. Look to the work plan and you will see environmental justice is ignored. In this area I fault not only the Montana Office of EPA but Region 8's office in Denver which has an environmental justice staff. I was shocked to find that Region 8, unlike most EPA regions, does not even have an environmental justice action plan.
- 13. Environmental Justice (EJ): The Butte community has clear EJ concerns given its elevated poverty rate in areas most impacted. Specific concerns adequately expressed in prior comments are:
 - How the housing stock (quality, design, size, etc.) might influence exposure in ways that differ from common risk assessment assumptions?
 - How potentially lower health status among low income people increases susceptibility?
 - Potential synergistic effects of exposure to multiple contaminants.
 - How this and future health studies will avoid inadvertent discrimination against low-income residents?
 - In what ways are those most affected, i.e. low income people, directly involved in the health studies?
- D. Comments Pertaining to Independence of Study/Investigators and Need for External Peer Review
 - Comments question the independence of the study and its investigators, and cite the need for external peer review of the study.
 - Response TBD.
- 1. Simply put, after reading the draft work plan, I am convinced that it is inadequate in design, scope, methodology, reliability and validity. It is designed simply to prove, as has already been articulated by the Butte Health Department even before the study has been conducted, that Superfund is working to protect human health.

The Health Study announces the results of the study before the study is even done. This is an egregious example of poor and sloppy, as well as biased, investigation on the Health Department's part.

Citizens were promised an independent health study. We are not getting an independent health study. Because the Health Department lacks the expertise to do such a study, we are getting the same old story of the EPA and the PRPs evaluating their own work. How can the public have any confidence in such an approach? Isn't there a potential for bias here? The Health Department is simply going along and will rubber stamp whatever EPA and the PRPs come up with as their conclusions.

- 2. Any future health studies need to be conducted by an independent and highly qualified investigator (s). The public needs assurance that future health studies will be totally unbiased.
- 3. Issues regarding the independence and validity of the study need to be addressed. This Health Study, so far, is just another case of the agencies who have done the work so far in Butte evaluating the effectiveness of their own work. How can the public, at present, have any degree of confidence that this will be an independent, valid and unbiased study? At a minimum, the design and conduct of the Health Study needs to be subjected to outside, independent peer review from an entity not connected to or part of the EPA, MDEQ, ARCO or Butte/Silver Bow.
- 4. The Atlantic Richfield Company/British Petroleum Company is funding the study and they hired and chose the contractor conducting the study. I have absolutely no doubt that the local people currently involved with the Health Study of this committee are good folks and are trying to do what is right. The problem they face is that as long as they receive their research and information from the Federal and State agencies, and the Atlantic Richfield/British Petroleum Company their research is always going to be suspect.
 - I have said for years that Butte needs an unbiased analysis by some independent environmental research firm or University outlining what truly is necessary to have a responsible cleanup and restoration of the Community. The same holds true for this health study---Butte needs a totally independent analysis of the health situation of the community. Until this happens, folks from Butte will always be suspect.
- 5. The consulting firm chosen to perform the study has been intimately involved with ARCO for many years. These people are not independent, third-party experts.
- 6. The needs to be independent, peer review of the whole development and execution of the Butte Health Study.
- 7. Butte citizens question the independence and validity of the study. It is the old story of the EPA evaluating itself and finding that it has done a good job. This Health Study has no credibility in the community.
- 8. The whole Health Study design and execution should be subject to independent peer review.
- 9. The ability for Atlantic Richfield and their consultant, Environ, to conduct a study with unbiased use of prior collected data, and to draw conclusions that might be critical of their work to date. Without trust, or processes that stakeholders agree can operate independent of trust, the chances of achieving objective and widely recognized conclusions are greatly diminished.

- E. Comments Pertaining to Specific Study Design Elements of the Draft Work Plan
 - Comments relate to various specific study design elements included in the draft work plan.
 - Responses TBD.
- 1. Need to compare Butte to: (a) a same size city, with similar rates of alcohol consumption, obesity and smoking, that does not have a heavy metals problem, (b) to a same size city, with similar rates of alcohol consumption, obesity and smoking, that has a heavy metals problem similar to Butte and (c) to a city similar to Butte in terms of size and contamination that has undergone extensive Superfund remediation. This city would have similar rates of alcohol consumption, obesity and smoking.
- 2. p. 17, 1st and 2nd bullets, Section 2.3.3, Step 3: Identify the Information Inputs: Please explain why "representative distributions" are needed as it relates to the planned assessment criteria. A community level response seems inconsistent with the individual level response identified on page 7 of the RMAP. Also, it seems you need representative data within neighborhoods rather than "within the Butte community" to meet the first line of evidence listed as bullet 1 at the bottom of the page. Please clarify what those neighborhoods are and why a neighborhood approach is important. Also, what about arsenic and mercury biomonitoring data needs? Also, enough is known to state at this point in the Draft Plan at some level of professional judgment if the available data meets your input needs, and if not, what needs to be done.
- 3. p. 17, possible new bullet, Section 2.3.3, Step 3: Identify the Information Inputs: Please address the potential for exposure via groundwater as another route of exposure.
- 4. p. 18, 2rd paragraph (not including bullets), Section 2.3.4 Step 4: Define the Boundaries of the Study: The area is restricted to BPSOU's RMAP, but most of the data has been collected from the Butte-Silver Bow County; how are they to be compared? It seems the study boundary needs to match the areas for which there are data? Also, as we consider alternative studies beyond evaluation of available blood-lead data, the study boundary may need to be modified. Perhaps the study boundary needs to be stated in more general terms, the greater Butte community, with individual studies focusing on sub-parts consistent with the available data?
- 5. p. 18, 3rd paragraph (not including bullets), Section 2.3.4 Step 4: Define the Boundaries of the Study: Please clarify what is meant by "the target populations of interest are young children...and pregnant mothers." Does this apply to all metals? Are others therefore excluded? CTEC believes that protections should be extended to all persons.
- 6. p. 19, 1st paragraph, Section 2.3.5. Step 5: Develop a Decision Rule: Why should statistical measures of significance be decided later? What factors might lead to higher or lower limits? At a minimum, the role of oversight agencies and the public in this important decision-making process should be detailed at this point in the document.
- 7. p. 19, Section 2.3.6 Step 6: Specify Tolerable Limits on Decision Errors: There are no limits specified in this section. Rather, what is given are more in line with Decision Rules. Also, it's not clear why statistical differences across neighborhoods or comparative temporal trends across communities are needed. The central point seems rather to get blood lead levels down to acceptable levels for all people who chose to participate in the voluntary cleanup program.

- 8. p. 19, paragraph 4, Section 2.3.6 Step 6: Specify Tolerable Limits on Decision Errors: The three data needs seem to belong in a prior section. Again, more planning thought and assessment should go into this plan regarding the ability of existing data to meet the proposed decision rule needs. Otherwise, we risk a major change to the plan outside of the existing agency review and public participation process.
- 9. p. 20, Section 2.3.7, Optimize the Design for Obtaining Data: Reiterating the last comment, this plan should not be approved until these optimization tasks are complete. Details for how the quality assurance review of RMAP data is to be done should be provided. Reference communities (if really needed) should also be selected prior to approval of the plan. The public should have the chance to review and comment on these procedures.
- 10. p. 22, paragraph 7, Section 2.4.4 Task 4 Data Compilation: More detail is needed on how confidential information is to be handled throughout this study. Appendix D only describes the transcription process, not the storage, analysis and reporting of data put into electronic files. Bits and pieces of good information are provided in pages 7 to 9, 21, 23 and Appendix D in ways that are hard to integrated and understand. Page 6 mentions "participant and neighborhood coding", yet page 8 mentions names and addresses, among other fields of information in the data file. Questions on details remain, such as: how is coding done, how many people have access to confidential information, how is access controlled, how is biomonitoring data connected with yard and house data, and how is quality control in transcription being done? A discussion on these points may be more helpful than a written response.
- 11. p. 23, Section 2.4.5 Task 6 Data Analysis and Reporting: Detail, perhaps alluded to elsewhere, is needed regarding agency and public participation review procedures associated with a draft and final report. Also, some reconnecting of the "recommendations for future improvements" to the five-year reassessment process may be appropriate.
- 12. Dust needs to be a focus of the study.
- 13. A complete and thorough investigation of attic dust needs to be part of the study.
- 14. Methodology: Many concerns have been expressed about the methodology for the current blood lead study and future studies:
 - Clarifying the limitations associated with current blood lead data, including elevated
 detection limit concerns, other data quality limitations, representation (particularly for low
 income neighborhoods), and statistical power to evaluate significant differences on a
 neighborhood and/or community wide basis.
 - Addressing risk from exposure to chemicals other than lead, and considering possible affects of combined exposure.
 - Release and use of existing urinary arsenic data.
 - Methods for addressing disease incidence and mortality in ways that are more constructive than has been achieved through the kind of "dueling expert" approach that has been thus far fostered though the health study process.
- 15. While a written response to all prior comments submitted is expected, CTEC does not believe that this kind of back-and-forth will be adequate to resolve all our concerns. Moving forward, CTECs direct involvement with the Citizens' Advisory Committee provides the possibility of achieving a

huge step forward in addressing our concerns. However, as achieving more common understanding will take time, we request the following short-term changes to planned work:

- Re-assess the schedule and process for conducting the blood lead study. There are too many concerns about the objectives, validity and methodology for the current blood lead study to expect quick and easy resolution. Any attempt at a response to comments with a final study plan, followed within a few short months by a draft study is likely to lead to an ongoing "dueling experts" approach and lack of agreement on study conclusions. This will not achieve the objective of enabling Butte citizens to achieve understanding of any remaining community health needs, as it applies to lead exposure in this case. CTEC recommends that we move to a phased approach that begins by framing up the broader objectives of the health study (over the long term) versus short-term objectives (of the blood lead study), clarifying relevant EJ questions and response methods, and then proceed in step-wise fashion to evaluate the blood lead data. For example, we might first address data quality and representation concerns before addressing other study questions. While perhaps slower, we believe this approach will result in less written comment and response, less redoing of work, and more community involvement leading to improved common understanding. So while slower, it need not be any more costly than the current approach and stands a much better chance of achieving overall goals.
- Apply state-of-the-art process expertise for conducting the remainder of the health study. This health study involves technical complexity, disparate stakeholder interests, and social controversy that is at least partially rooted in risk perception influences. EPA has established programs that provide state-of-the-art expertise and procedures to meet exactly these kinds of challenges. EPA's Alternative Dispute Resolution program (http://www.epa.gov/adr/cprc_adratepa.html) is a prime example. We recommend that the study team give full consideration to the use of these resources to meet the longer-term aspirations of the health study.

F. Comments Pertaining to the Study Focus on Exposure vs. Health Outcomes

- Comments relate to limitations of the initial study design on exposure to lead and assert the need to evaluate health outcomes instead.
- Response will clarify the rationale for focusing the initial study design on exposure to lead instead of evaluated health outcomes. Revisions to the work plan will also be made to clarify these points.
- 1. Future health studies in Butte need to look answer the following questions:
- How do the contaminants of concern impact the health of Butte residents?
- What is the relationship in Butte between exposure to the toxics of concern and diseases such as cancer, diabetes, ALS, multiple sclerosis, etc.? "In the realm of environmental health, epidemiologic research generally aims to portray the frequency of disease occurrence in the population or to link disease outcomes to specific exposures." (Environmental Epidemiology, Jones and Bartlett Learning, p. 29)
- What are the health effects Butte residents experience from exposure to the toxics of concern?

- What proportion of disease in the population of Butte/Silver Bow would be prevented if exposure to heavy metals were significantly reduced?
- Is Butte safer today than before Superfund commenced its cleanup activities?
- What are the chronic as compared to the acute effects of exposure to the toxics of concern? "In environmental epidemiology, concern usually centres on chronic effects from low-level exposures." [Lesley Rushton and Paul Elliott, Institute for Environment and Health, "Evaluating evidence on environmental health risks," British Medical Bulletin [2003]68 (1)]
- Need to focus on incidences of disease.
- Need to rely much less on incidence studies. For example, many low-income residents don't have ready access to health care providers or services. Low-income citizens would therefore, contrary to EPA's environmental justice mandate, be underreported and underrepresented if future health studies rely extensively on incidence studies.
- 2. Inadequate assessment of epidemiology information: Section 4.1 of the RMAP (p. 7) provides several different requirements for the health studies, including, "compiling and interpreting the morbidity and mortality statistics as an epidemiology study, and compiling and interpreting influencing factors (environmental or cultural) for mortality rates". Only three paragraphs of the Draft Plan are focused on meeting these objectives (see page 2) with reference to brief summary of prior work done by ATSDR (provided in Appendix A). However, there is no critical examination of the thoroughness of ATSDR's work. We note for example that one of the more common types of cancers caused by arsenic, squamous cell carcinoma, is not reportable and not assessed. What might be done to overcome this limitation? Also, non-cancer endpoints are not addressed. Lastly, the three paragraphs of Draft Plan text conclude with a reference to epidemiological studies that might be of interest to future public health studies, but no details are given as to if, when or how this interest might be addressed.
- 3. General Comment Summary and Proposed Actions: The core issue underlying our General Comments is the desire to constructively identify what kinds of epidemiological studies might be done in the future that would improve our understanding of the health protectiveness of the remedy. CTEC is concerned that thus far there has been inadequate involvement by qualified epidemiological researchers. A highly polarized, dueling science kind of debate has been going on this past year, often through the media, that has undermined public understanding of and trust in the science. While we support moving forward with the biomonitoring assessment, CTEC proposes a separate track to assess possible options for future 5-year health studies. We believe this process needs to start by more thoughtfully considering the kinds of questions the studies need to ask, better understanding the limitations of what existing epidemiology can do to answer the study questions, what kinds of new epidemiology data is maybe needed, and what other kinds of studies such as ongoing biomonitoring should be conducted into the future.
- 4. Anyone who lives in this community and does not believe that the cancer rates and other diseases like MS, emphysema in adults, asthma in our children, and other lung related diseases are not higher in Butte than in other communities in Montana is naive!
- 5. The study proposes to analyze some blood lead data. Blood lead is not "health." Thus, you should not call the proposed project a "health study."

- 6. The blood lead program in Butte has many deficiencies, but ARCO/EPA did not design the program to be a comprehensive or conservative marker of exposure in Butte. They chose a small subset of the population to test, some of whom (i.e., pregnant women) happened to show the lowest blood lead levels in the 1990 University of Cincinnati study (also funded by ARCO). Thus, the data will be biased towards lower concentrations.
- 7. The blood lead program has been very limited to whom is/was eligible for testing.
- 8. The blood lead data will not be sufficient to understand risks because the instrumentation used to analyze the samples had a detection level that was too high. (For example, recent medical research has shown behavioral and learning problems in children and young adults at much lower blood lead levels than the detection limit used in the Butte program.)
- 9. Lead is only one of the contaminants of concern in Butte. Arsenic exposure should also be a primary focus. While the EPA has publicly claimed to have years of urinary arsenic data, it is not true.
- 10. Samples of soil and dust in Butte have indicated that the contamination is not evenly-spread throughout Butte and Silver Bow County; thus, a comprehensive health study of disease rates, mortality rates, and other health-related problems on neighborhood scales is needed.
- 11. I completely agree with each of Dr. Peterson's points. I can only hope the members on this routing list and on the study committee take the time to investigate each of her points. She is a highly educated expert in this matter and can back up each of these statements with a plethora of references. Lead is not the chief or only contaminant in the BPSOU or surrounding areas and it is both misleading to the public and unscientific to present a study of blood lead levels as a comprehensive health study or an indication of risk or toxic effects stemming from exposure to other contaminants. There has been absolutely no attempt to understand the chemicals as a mixture, either. This study is being done this way because EPA, ARCO, and their researcher believe that they already know the outcome of the study based on the results of blood lead studies done in recent years. This is the same reason they are willing to look at incidence rates.

 In my dissertation, I reported the lower incidence rates for Butte-Silver Bow versus the rest of the State. I found it amusing that they put this forward as new information after my study. I think there are several compounding reasons for the lower incidence rates, but that is another topic for another
 - I have tried my best to stay out of this as well, because my previous involvement was a truly atrocious experience, but obviously care very deeply about the issue and am having a hard time remaining silent. I think it is truly incorrect and deceptive to present this current study to the public as anything other than a blood lead study and I think the public deserves to know if there are health issues in the community and if so, what can be done about them. There are several things, such as calcium supplementation, that could be promoted to prevent lead and other metal absorption, but instead of looking into this type of practical solution the powers that be are instead spending time and energy defending themselves and their previous actions.

 I, for one, am truly disappointed.
- 12. The Health Study has been unjustifiably limited to, not a health study, but an exposure study. Doing so is a disservice to the Butte community and is an unjustified and unwarranted limitation of the Health Study. The argument that there are many potential causes of diseases that are related to the toxics found in Butte is not persuasive. It repeats the old and tired argument that industry

constantly uses that we can never know whether or not a particular toxic directly causes a specific disease.

We know that the toxics found in Butte such as lead, arsenic, mercury, zinc, cadmium, etc. cause disease. As a member of the public, I want to know whether or not the incidences of diseases and mortality rates related to the toxics found in Butte are decreasing.

- 13. The "safe" levels of exposure to toxics found in Butte are constantly being tightened. What was considered a "safe" level a few years ago is no longer considered "safe". For example, consider how so called "safe" levels of exposure to lead are constantly being reduced. What was a safe level of lead exposure five years ago is no longer considered "safe" today.

 By concentrating only on exposure to toxics, the non-Health Study the EPA has mandated by unilateral order misses the point. Superfund is supposed to protect the public health. The central question is whether or not Superfund is protecting the public health. This can only be determined by looking at incidences of mortality and disease related to the toxics found in Butte. By examining only levels of exposure and then saying, based on exposure levels, that Superfund is working to protect the public health is a fallacious, non-protective process. What might be a "safe" level of exposure today may not be safe tomorrow. However, we can tell whether or not the public's health is being protected by looking at mortality and disease rates related to toxics found at Butte Superfund sites.
- 14. On Wednesday, May 16, 2012, the CDC announced a tougher standard for what constitutes lead poisoning for children. The new standard for lead poisoning is set at 5 micrograms of lead per deciliter of blood.

The old standard was 10 micrograms. The old standard was adopted in 1991. Until May 2012, the CDC, EPA, etc., all strongly maintained that the 10 microgram standard was fully protective of children's health re lead exposure. Now the CDC says the standard needs to be tougher, the old standard is not protective.

My point regarding the Health Study, is that focusing only on exposure misses the point. The study should focus on disease incidence and mortality rates.

What is a protective standard today may well not be considered protective in the future. Acceptable lead exposure limits have consistently been tightened over the years. The question that should be asked is: Are Butte citizens, particularly low-income citizens, experiencing diseases relative to the toxics found in Butte? We do not need to continue the failed practice of saying that exposure limits to lead are ok in the Butte populace because they are below the action levels. the current action level for lead in Butte is not protective. As the case cited above attests, exposure may be below the action levels and still not protective of human health. If so, Superfund is not working and should be reevaluated.

- 15. The Health Study needs to focus on chronic exposure not just acute exposure to the toxics on the Butte Hill if the Health Study wants to get a true picture of Butte's health as it relates to the Superfund cleanup.
- 16. Mortality rates and disease rates need to be studied on a neighborhood and not just a Silver-Bow County basis.
- 17. The health effects of lead on adults needs to be considered as well as the health effects on children. While critical, focusing on children is not enough. Again, to get a true picture of Butte's health we need to look at exposure levels, disease rates and mortality rates for those diseases linked to

- exposure to the toxics on the Butte Hill for ALL age levels. Failure to do so contaminates the results of the study.
- 18. A monitoring system for disease and mortality rates needs to be implemented.
- 19. Mortality rates and disease rates for those diseases linked to exposure to the toxics on the Butte Hill need to be tracked in the future.
- 20. Clarifying the difference between the blood lead exposure study and broader health study objectives that are expected to be more epidemiological in nature.

G. Comments Pertaining to focus on Lead

- Comments relate to the focus on lead vs. other constituents in the initial health study work plan.
- Response will clarify the rationale for focusing the initial study design on exposure to lead instead of other constituents. Revisions to the work plan will also be made to clarify these points.
- 1. Need to consider exposure to all heavy metals, not just arsenic, lead and mercury.
- 2. Need to consider the additive bio-accumulative, synergistic and antagonistic effects of exposure to heavy metals.
- 3. Need to be actually monitoring of urinary arsenic in Butte.
- 4. p. 6, 1st paragraph, Section 2.1.2, Overview of the RMAP: The current plan for collection of arsenic and mercury biomonitoring data has not resulted in the collection of adequate data to evaluate the effectiveness of Superfund remediation. There should be a commitment to reconsider the current approach as part of a broader commitment to consider additional studies in future years, beyond the currently proposed blood-lead data evaluation.
- 5. More than just the so called toxics of concern need to be evaluated. The Health Study should not just focus on lead, mercury and arsenic.
- 6. Testing for urinary arsenic needs to be done whether or not dust samples in the home show elevated levels of arsenic.
- 7. In addition to the additive, synergistic and bio-accumulative effects of exposure to the toxics on the Butte Hill, consideration must be given to the antagonistic effects of exposure to the various toxics on the Butte Hill.
- 8. Hair and fingernail sampling for arsenic exposure should be part of the Study as this gives a better picture of chronic exposure in Butte to toxics.

H. Comments Pertaining to the Precautionary Principle

- Comments request that the Precautionary Principle inform and guide the health study.
- Response TBD.
- 1. Future health studies need to fully incorporate the precautionary principle. "The precautionary principle is, in fact characterized precisely because it states that the lack of a full scientific certainty should not be a reason for postponing the adoption of appropriate preventive measures in relation to a specific risk factor, when there is a reasonable but not certain reason to consider it so.

 According to the precautionary principle, the uncertainty of data loses a big part of its paralyzing

power because the principle reverses the burden of proof. Indeed this principle does not ask to show that there is a certain risk in some exposures to those who wish to intervene with preventive action, but instead it asks to those who don't want to intervene to show that there is no risk. In environmental epidemiology, moreover, uncertain risks are still risks which are individuated by scientific procedures, and the degree of uncertainty of the results does not always undermine the risk of the occurrence of adverse effect on human health (uncertainty may regard the ability of a study to measure the risk, not the existence of the risk itself)." (Gordana Pagliarani and Caterina Botti, "Prevention, communication and equity in environmental epidemiology: ethical issues," Ann 1st Super Sanita 2011, Vol. 47, No 3) The precautionary principle fits nicely into the retroactive, strict, joint and several liability scheme of Superfund.

2. I ask that the Precautionary Principle inform and guide the Butte Health study. This principle is part of both federal as well as Montana law.

The essence of the precautionary principle is that government should act before harm to human health and the environment occurs from the releases of toxic substances. The precautionary principle "dictates that indication of harm, rather than proof of harm, should be the trigger for action." (Sandra Steingraber, Living Down Stream: An Ecologist Looks at Cancer and the Environment, p. 270.) If there is a reasonable suspicion that harm to human health and the environment could occur from the release or presence of a toxic substance, government should step in and fix the problem before its hurts people and the environment. The 1998 Wingspread Statement on the Precautionary Principle states: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically." Former EPA director Christine Todd Whitman stated: "policymakers need to take a precautionary approach to environmental protection. . . . We must acknowledge that uncertainty is inherent in managing natural resources, recognize it is usually easier to prevent environmental damage than to repair it later, and shift the burden of proof away from those advocating protection toward those proposing an action that may be harmful." If there is a strong suspicion that something bad is going to happen, government has an obligation to stop it prior to its occurring. The precautionary principle is really grounded in old common sense sayings: "An ounce of prevention is worth a pound of cure." "Better safe than sorry." "A stitch in time saves nine." "Look before you leap."

The President's Council on Sustainable Development supports the precautionary principle. The Council declared: "Even in the face of scientific uncertainty, society should take reasonable actions to avert risks where the potential harm to human health or the environment is thought to be serious or irreparable." The American Public Health Association has passed a similar resolution concerning chemical exposure. (Resolution 9606)

The U.S. Court of Appeals for the District of Columbia Circuit upheld the EPA's use of the precautionary principle in Ethyl Corp. v. U.S. Environmental Protection Agency (541 F. 2d 1, 6 ELR 20267 (D.C. Cir.), cert denied, 426 U.S. 941 (1967) This was the case which supported the banning of leaded gasoline by the EPA. The banning of lead additives to gasoline was an example of the precautionary principle in action. "The U. S. Court of Appeals for the D.C. Circuit upheld the U.S. Environmental Protection Agency's decision to take a precautionary approach and ban lead anyway, even in the absence of scientific evidence adequate to demonstrate exactly what the risks from the

lead were or what the benefits of removing it would be. As it turned out, banning leaded gasoline was the single most important contributor to the virtual elimination of lead from air and from most children's blood." (Charnley and Elliott, Risk Versus Precaution: Environmental Law and Public Health Protection, Environmental Law Institute, March 2002)

There is ample support for the precautionary principle from international organizations and treaties, to many of which the United States is a signatory. For example, the Rio Declaration from the 1992 United Nations Conference on Environment and Development, also known as Agenda 21, stated: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." The United States signed and ratified the Rio Declaration.

The precautionary principle is also part of the following: Ozone Layer Protocol, Second North Sea Declaration, United Nations Environment Programme, Nordic Council's Conference Declaration of October 18, 1989, PARCOM Recommendation 89/1, Third North Sea Conference, Bergen Declaration on Sustainable Development, Second World Climate Conference, Bamako Convention on Transboundary Hazardous Waste into Africa, OECD Council Recommendation of January 1991, Maastricht Treaty on the European Union, Climate Change Conference, UNCED Text on Ocean Protection, and the Energy Charter Treaty.

The precautionary principles would encompass far more than just looking at exposure data. My point is that it is a specious argument that we cannot look at incidences of disease because the specific cause of a disease cannot be traced to a specific toxic.

If the incidence of diseases associated with toxics found in Butte is not decreasing or actually increasing, something is wrong. If disease rates for diseases associated with the toxics found in Butte are steady or increasing, as the Barry report found, the ROD for Priority Soils should be reopened to deal with the diseases associated with the toxics found in Butte. We can of course only ascertain the above if we expand the scope of the Health Study to look at mortality rates and disease rates, not just exposure data. To confine the study to exposure data is unwarranted and inimical to the public interest.

- 1. Comments Pertaining to Other Various Issues
 - Comments relate to various issues not otherwise captured under themes detailed above.
 - Responses TBD.
- 1. The Butte Silver Bow Health Department and EPA need to coordinate what they are doing. It appears, at present, that the BSB Health Department and the EPA are on parallel, independent tracks regarding future health studies. Such a situation could lead to the same problems experienced earlier, i.e. the Health Department develops a health study proposal that does not fit EPA's requirements and is rejected by EPA for not meeting the requirement and terms of the unilateral order.
- 2. Need to incorporate hair and fingernail sampling.
- 3. Need to have adequate funding provided for future health studies.

- 4. The practice of averaging across age groups needs to be ended. Such averaging distorts the true picture of Butte health and is poor statistical practice.
- 5. Local health impacts to Butte children associated with lead exposure have been reduced by the Multi-Pathway Residential Metals Abatement Program, but all body burden sources of lead should be considered including not only lead based paint dust and chips, but also nuisance dust, drinking water and air.
- 6. Potable Drinking Water is a necessary resource, and our Community system has been greatly improved and provides good water. But, it is possible to have near home contaminants associated with old lead taps, old lead pipes and older solder with higher than acceptable lead levels. We should be aggressive with the EPA Lead and Copper Rule and check for lead in all the old systems, not just the required sample sites. Private Water Wells should be evaluated, when possible, for lead, arsenic and other issues.
- 7. As a lifelong Butte resident and a former seven-term member of the Montana House of Representatives, I have been directly involved with the Superfund cleanup issue in Butte for over thirty years. I served in the Legislature when the Atlantic Richfield Company closed the Smelter in Anaconda and closed the Berkeley Pit and Butte Mines. I have a good historical perspective on this issue and the positives and negatives of mining and the cleanup and restoration of this community. I believe the Environmental Protection Agency, the State of Montana, the Atlantic Richfield/British Petroleum Company and the Local Government have failed this community in protecting the health and the environment of the Community and to providing a responsible cleanup and restoration of our community, as required by law and the Constitution.
 - A couple examples of the type of cleanup we have received; the Berkeley Pit currently contains over 42 billion gallons of toxic water and continues to rise---Georgetown Lake contains 10.1 billion. We have learned since the Record of Decision was issued on Butte Priority Soils that the groundwater in the Parrott Tailings area around the Civic Center is more toxic than Berkeley Pit Water and many experts believe a plume of toxic groundwater is spreading out over the town from that area and further contaminating the community.
- 8. Several months back a very reputable Butte resident, Stacy Barry, prepared a Doctorate Dissertation on the cancer rates in Butte. She prepared this information under the advice and assistance of professors from Montana Tech and the University of Montana outlining the facts. The way the Environmental Protection Agency, the State of Montana, the Atlantic Richfield/British Petroleum Company have dealt with this research was to "kill the messenger" rather than dealing with the message.
- 9. I am currently involved along with Sister Mary Jo McDonald and Ron Davis as members of the Silver Bow Creek Headwaters Coalition in a lawsuit concerning the name of Silver Bow Creek flowing through Butte.
 - The agencies and ARCO continue to call Silver Bow Creek flowing through Butte Metro Storm Drain, even though they know it is not Metro Storm Drain and its proper legal name is Silver Bow Creek. We believe the State's repeated references to Silver Bow Creek flowing through Butte, as the "Metro Storm Drain" in public documents and other references are illegal, and degrade the Creek's status as the headwaters of the Clark Fork and Columbia Rivers.

- We also believe the reason they chose and continue to call it Metro Storm Drain is so they will not have to provide the responsible cleanup and restoration of this section of Silver Bow Creek that is now taking place on the Creek from Interstate 15 to the Warm Springs Ponds. Unbelievable!
- 10. Butte citizens are not happy with the whole Health Study process.
 - From its inception the Health Study process has been problematic. It appears that the Health Study process that we are going through at the present was necessitated because the EPA did not like the results of Stacie Barry's study which showed that Superfund had serious problems in Butte. In all my years of involvement in Superfund, I have never seen such a "hatchet job" done on a study and the author of that study.